



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

DATE MAILED: 04/15/2004

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/833,838	04/10/1997	BRUCE D. GAYNOR	96700/451	3053
75	90 04/15/2004		EXAM	INER
AMSTER ROTHSTEIN & EBENSTEIN			EWOLDT, GERALD R	
90 PARK AVENUE NEW YORK, NY 10016			ART UNIT	PAPER NUMBER
		•	1644	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
		GAYNOR ET AL.			
Office Action Summary	08/833,838 Examiner	Art Unit			
,					
The MAILING DATE of this communication a	G. R. Ewoldt, Ph.D.	correspondence address			
Period for Reply	ppears on the cover sheet with the	conceptinuonee adarese			
A SHORTENED STATUTORY PERIOD FOR REF THE MAILING DATE OF THIS COMMUNICATION - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a re - If NO period for reply is specified above, the maximum statutory perions - Failure to reply within the set or extended period for reply will, by state that the period for reply will, by state the period for reply will, by state that the main three months after the main terms of patent term adjustment. See 37 CFR 1.704(b).	1. 1.136(a). In no event, however, may a reply be to exply within the statutory minimum of thirty (30) digits will apply and will expire SIX (6) MONTHS froute, cause the application to become ABANDON	timely filed ays will be considered timely. m the mailing date of this communication. IED (35 U.S.C. § 133).			
Status					
1)⊠ Responsive to communication(s) filed on 10	October 2003.				
	· · · · · · · · · · · · · · · · · · ·				
Disposition of Claims					
4) ☐ Claim(s) 54-58 and 71-75 is/are pending in the 4a) Of the above claim(s) is/are withdrest is/are allowed. 5) ☐ Claim(s) is/are allowed. 6) ☑ Claim(s) 54-58 and 71-75 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and	rawn from consideration.				
Application Papers					
9) The specification is objected to by the Exami	ner.				
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the	Examiner. Note the attached Offic	e Action or form PTO-152.			
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreignal All b) Some * c) None of: 1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the priority application from the International Bure * See the attached detailed Office action for a list 	nts have been received. nts have been received in Applica iority documents have been receiv au (PCT Rule 17.2(a)).	tion No ved in this National Stage			
Attachment(s)					
1) Notice of References Cited (PTO-892)	4) Interview Summar	y (PTO-413)			
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0 Paper No(s)/Mail Date 	Paper No(s)/Mail [

1

DETAILED ACTION

- 1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment and remarks, filed 10/10/03, have been entered.
- 2. Claims 54-58, 71-74, and newly added Claim 75, are being acted upon are pending.
- 3. In view of the instant amendment and response, the previous rejection under the first paragraph of 35 U.S.C. 112 has been withdrawn. In particular, Applicant's showing through the submission of the reference of Sharma et al. (2003) that the peptides of the instant claims are capable of binding the R4A antibody in a relevant *in vitro* model (ELISA), and the limiting of the method of the claims to a method of inhibiting antibodies that bind the same epitope as R4A, has overcome the rejection.
- 4. The following are new grounds for rejection.
- 5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 54-58, 71-74, and newly added Claim 75, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, Claim 54 is nonsensical. It appears that Applicant has inadvertently removed the word "antibody" from line 3 such that the claim now reads "A method of inhibiting binding of an anti-double stranded (ds) DNA to glomeruli of renal tissue in a subject...", . The method should recite "A method of inhibiting binding of an anti-double stranded (ds) DNA antibody to glomeruli of renal tissue in a subject..."

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 54-58, 71-74, and newly added Claim 75 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, the recitation of:

A) "A method ... wherein the anti-ds antibody binds to the same epitope as an R4A antibody" in Claim 54.

Applicant's amendment, filed 10/10/03, asserts that support for the new limitation can be found at page 11, line 28 through page 12, line 1, of the specification. Support, however, has only been found for the R4A antibody and not antibodies which bind the same epitope.

- 9. No claim is allowed.
- 10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.
- 11. Please Note: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600

G.R. EWOLDT, PH.D. PRIMARY EXAMINER